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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/419,461	10/15/1999	OMAR S. KHALIL	6351.US.P2	1303
23492	7590	05/23/2005	EXAMINER	
ROBERT DEBERARDINE ABBOTT LABORATORIES 100 ABBOTT PARK ROAD DEPT. 377/AP6A ABBOTT PARK, IL 60064-6008				KREMER, MATTHEW J
ART UNIT		PAPER NUMBER		
3736				DATE MAILED: 05/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	09/419,461	KHALIL ET AL.	
	Examiner Matthew J Kremer	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 28 February 2005.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,2,8-12,15-20,26-30,33-38,44-47 and 49-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-2,8-12,15-20,26-30,33-38,44-47 and 49-53 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Terminal Disclaimer

1. The terminal disclaimer filed on 2/28/2005 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent 6,662,030 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Objections

2. Claims 1 and 19 objected to because of the following informalities. Claim 1 recites the limitation "said at least one parameter of said biological sample" in line 32 in which there is insufficient antecedent basis. Claim 19 recites the limitation "said at least one parameter of said biological sample" in line 33 in which there is insufficient antecedent basis. Appropriate correction is required.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-2, 8-12, 15-20, 26-30, 33-38, 44-47, and 49-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,978,691 to Mills in view of the journal publication "Effect of temperature on the optical properties of ex vivo human dermis and subdermis" by Laufer et al. (Laufer)(cited by Applicant) in view of U.S. Patent 5,497,769 to Gratton et al. (Gratton). Mills discloses a method and apparatus for monitoring blood parameters which makes use of measurements of the behavior of substances which are affected by temperature. (column 1, lines 16-25 of Mills). Mills teaches that to generate data, the temperature induction means is used to bring the finger (or tubing or other space of interest) to a known temperature, light of known wavelength and intensity is emitted on the surface of interest. (column 9, lines 1-33 of Mills). Detection of the light signal at a distinct point (normally opposing surface) is made and the relative absorbance and extinction of the signal is calculated. The process is repeated at the next chosen wavelength, while still at the same predetermined temperature. Once the desired number of wavelengths has been examined, the temperature induction means would bring the volume to a predetermined second temperature, and the data collection of steps would be repeated. At the completion of measurements and determinations for this second temperature, the temperature induction means will bring the space to a third predetermined temperature, and the measurements and determinations repeated. This process would be continued until the desired range of temperatures has been sampled. Mills does not explicitly disclose that the first temperature corresponds to a first depth in the body part and the second temperature corresponds to a second depth in the body part. Laufer presents a

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study on the influence of temperature on the optical properties of human dermis and subdermis. Laufer discloses that there is a decrease in the scattering coefficient for the subdermis and an increase for the dermis with temperature. (page 2488 of Laufer). This implies that at different temperatures, different layers are being measured in relation to reflected measurements since the average sampling depth of the measurements is shifting. Functionally, the method of Mills performs this operation since the fact that the average sampling depth in a tissue changes with temperature is a naturally occurring phenomenon. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Mills to include the fact that a temperature corresponds to the depth in a body part as disclosed by Laufer since the fact that the average sampling depth in a tissue changes with temperature is a naturally occurring phenomenon. The combination does not teach that the optical measurement is a spatially resolved diffuse reflectance measurement but the combination does teach the use of reflectance measurements (column 8, lines 1-3 of Mills) and the device can be used at a variety of places. (column 7, lines 55-59 of Mills). Gratton teaches a spatially resolved diffuse reflectance measurement (Figs. 1-2 of Gratton) that determines scattering and absorption coefficients. (column 3, lines 36-38 of Gratton). Gratton further teaches that providing such reflectance measurements allows measurements without the need to pass light through a narrow portion of tissue so that a more central area of the body can be used (column 2, lines 35-39 of Gratton). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify combination to include spatially resolved reflectance

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as disclosed by Gratton since Gratton provides reflectance measurements without the need to pass light through a narrow portion of tissue so that a more central area of the body can be used.

In regard to claims 8 and 26, Mills teaches that temperature of interest include 33 to 40 degree Celsius (column 13, lines 15-25 of Mills). In regard to claims 9-10, 27-28, and 44-45, Mills indicates that 660 and 940 nm are wavelengths of interest in oximetry in which these procedures can be used. (Fig. 11 of Mills). In regard to claims 11-12, 29-30, and 46-47, Mills teaches that glucose and hemoglobin can be measured. (column 13, lines 31-35 of Mills). In regard to claims 15-16, 33-34, and 49, Mills performs experiments on the finger. (Fig. 6 of Mills). In regard to claims 17-18, 35-36, and 50-51, Mills states that the invention can be used to determine sickle cell disease, certain cancers, and other diseases or conditions which are distinguished by markers in blood. (column 14, lines 11-25 of Mills).

5. Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,978,691 to Mills in view of the journal publication "Effect of temperature on the optical properties of ex vivo human dermis and subdermis" by Laufer et al. (Laufer)(cited by Applicant) in view of U.S. Patent 5,497,769 to Gratton et al. (Gratton) as applied to claim 37, and further in view of U.S. Patent 5,873,821 to Chance et al. (Chance '821). The combination does not teach the use of an endoscope. Chance '821 teaches that the oximeter can be disposed on an endoscope, catheter or guidewire or the like for examination of internal tissue. (column 6, lines 48-54 of Chance '821).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify combination to include an endoscope as disclosed by Chance '821 since an endoscope would allow examination of internal tissue.

6. Claim 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,978,691 to Mills in view of the journal publication "Effect of temperature on the optical properties of ex vivo human dermis and subdermis" by Laufer et al. (Laufer)(cited by Applicant) in view of U.S. Patent 5,497,769 to Gratton et al. (Gratton) as applied to claim 37, and further in view of U.S. Patent 5,931,779 to Arakaki et al. (Arakaki). The combination does not teach a particular distance between an emitter and a detector. Arakaki teaches that 1 mm is one such distance. (column 16, lines 3-10 of Arakaki). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the distance of Arakaki in the combination since a particular distance between an emitter and a detector is required and Arakaki teaches one such distance.

Response to Arguments

7. Applicant's arguments filed 2/28/2005 have been fully considered but they are not persuasive. The Applicant first asserts that Mills fail to disclose spatially resolved diffuse reflectance measurements of a biological sample. The Applicant also asserts that Laufer fails to disclose spatially resolved diffuse reflectance measurements of a biological sample. The Mills and Laufer references were not relied upon to teach

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spatially resolved diffuse measurements. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

The Examiner relied upon the Gratton reference for the teaching of spatially resolved diffuse reflectance measurements. Gratton teaches a spatially resolved diffuse reflectance measurement (Figs. 1-2 of Gratton) that determines scattering and absorption coefficients. (column 3, lines 36-38 of Gratton). Gratton further teaches that providing such reflectance measurements allows measurements without the need to pass light through a narrow portion of tissue so that a more central area of the body can be used (column 2, lines 35-39 of Gratton). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include spatially resolved reflectance as disclosed by Gratton since Gratton provides reflectance measurements without the need to pass light through a narrow portion of tissue so that a more central area of the body can be used. The Applicant has asserted that Gratton fails to disclose spatially resolved diffuse reflectance measurements of a biological sample. The Applicant argued that Gratton discloses the use of the same method of detection and circuitry as is used in frequency domain fluorometry and/or phosphorimetry, which are distinguishable from spatially resolved diffuse reflectometry. The Applicant primarily relies upon the teaching in column 4, lines 35-41 and column 6, lines 45-55 of Gratton. The Examiner takes the position that the Applicant has misinterpreted these passages. First, Gratton stated in column 4, lines 35-41:

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Typically, the method and apparatus of this invention make use of principles of frequency domain fluorometry and/or phosphorimetry which are well known, being disclosed for example in Gratton U.S. Pat. No. 4,840,485, Gratton et al. U.S. Pat. No. 5,212,386, and Gratton et al. application Ser. No. 07/983,829, filed Dec. 1, 1992, among others.

Even though Gratton discloses that the methods used in the Gratton reference are using the same principles as in frequency domain fluorometry and/or phosphorimetry, the assertion that Gratton reference is only teaching fluorometry and/or phosphorimetry principles is incorrect. Indeed, the column 6, lines 45-55 passage disclosed the principles of the Gratton invention as applied to spatially resolved diffuse reflectance measurements. Gratton teaches the determination of scattering and absorption characteristics based on the propagation of modulated light through tissue. (column 6, line 45 to column 7, line 52 of Gratton). The detectors are placed at different distances from the light source for the detection of light that has been scattered and absorbed by the tissue and the detectors are placed on the same side of the tissue as the light sources. (Figs. 1-2 of Gratton). These aspects of the Gratton invention are clearly spatially resolved diffuse reflectance measurements. Gratton's mere borrowing of principles from another form of measurements, i.e., fluorometry and/or phosphorimetry, does not change Gratton's basic teachings, which is spatially resolved diffuse reflectance measurements.

The Applicant also argues that Laufer is an invasive method that cannot be practiced on a biological sample comprising intact human tissue. The Applicant further argues that the tissue must be excised in the Laufer method and cannot be intact human tissue. The Examiner first would like to note that very similar arguments have

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been presented before the Examiner and the Board of Patent Appeals and Interferences (The Board). The Board has already affirmed the Examiner's rejections after considering these arguments. To remind the Applicant, such arguments are not persuasive since the information from Laufer discloses that the method of Mills causes the average sampling depth in a tissue to change when the temperature is changed. In other words, the change in the average sampling depth due to temperature change is a naturally occurring phenomenon. This naturally occurring phenomenon is inherent as a tissue property whether Mills discloses the phenomenon or not. The argument that the information is only applicable to excised tissue is not persuasive since Laufer teaches that the optical properties of skin is particularly relevant during noninvasive examination of brain and muscle tissue as well as glucose. (lines 4-6 of the Introduction of Laufer). Laufer is suggesting that the motivation for their experiments is to aid in the analysis of noninvasive procedures. This motivation would give an indication that the principles disclosed would be applicable in excised or intact tissue. In response to the Applicant's argument that the combination is a piecemeal construction, the Examiner disagrees. The Examiner is not excluding the concept that the Laufer reference is used on excised tissue but is applying the teachings from those experiments to indicate that there is a naturally occurring phenomenon of the change in the average sampling depth due to the change in temperature that is inherent in the method of Mills.

Since the rejections of claims 1-2, 8-12, 15-20, 26-30, 33-38, and 44-52 are deemed proper due to the reasons stated above and the applicant provides no other arguments than the supposed deficiencies of intact tissue and the failure of the

secondary references to teach the deficiency, the rejections of the subsequent dependent claims are also deemed proper.

8. Applicant's arguments with respect to claim 53 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J Kremer whose telephone number is 571-272-4727. The examiner can normally be reached on Mon. through Fri. between 8:30 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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